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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,625

03/01/2006

Gregoire Prevost

427.101

8272

47888 7590 09/04/2008  
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EXAMINER

MCDOWELL, BRIAN E

ART UNIT

PAPER NUMBER

4161

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,625	<b>Applicant(s)</b> PREVOST ET AL.	
	<b>Examiner</b> BRIAN MCDOWELL	<b>Art Unit</b> 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 5-20-2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/19/2006, 8/15/2008</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicant's election of group V in the reply filed on 5/20/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election without traverse of group V and election of specie (compound in claim 21) in the reply filed on 5/20/2008 is acknowledged.

Claims 1-20,24-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

An action on the merits of claims 21-23 is contained herein.

### ***Priority***

This application claims the priority date of 6/24/2004.

### ***Claim Objections***

The abstract of the disclosure is objected to because it is over the 150 word limit.

Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 103***

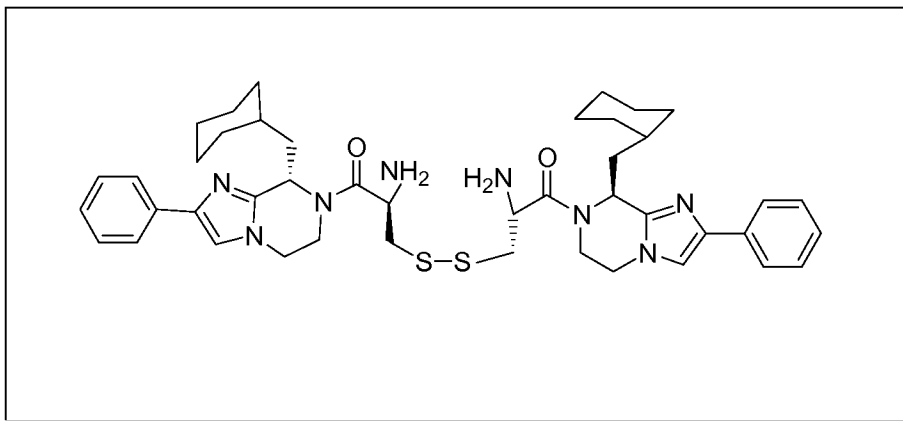
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

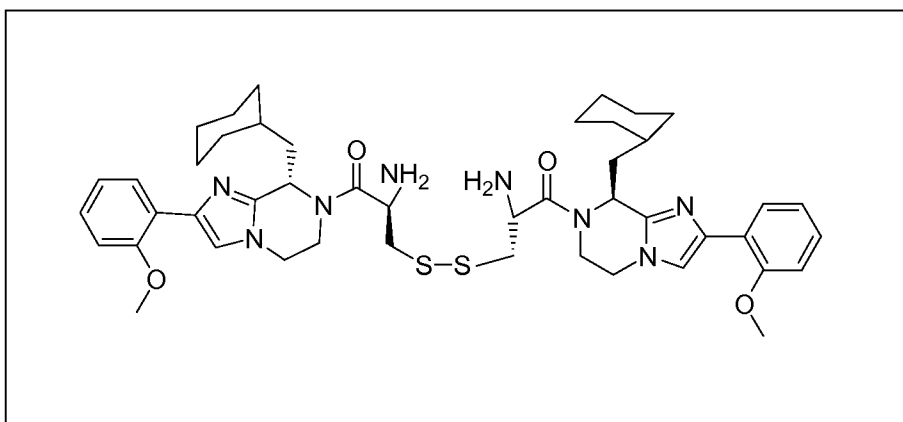
Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon *et al.* (WO 97/30053, mentioned in IDS by applicant, the document provided by applicant is defective and a new one has been provided herein).

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Claim 21 is drawn to the following pyrazine disulfide compound shown below:



Gordon *et al.* teach the following compound below (see compound 41, page 18):



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The only difference between the compound in claim 21 and the compound described by Gordon *et al.* is the lack or presence thereof an additional methoxy group (-OMe) on the phenyl ring. However, the genus formula in the Gordon *et al.* document teaches that the ring may be unsubstituted (see page 3, lines 17-19), thus hydrogen and the methoxy group are interchangeable.

Additionally, Gordon *et al.* teach a similar compound, wherein the phenyl ring is unsubstituted (see page 18, compound 38), that would provide motivation to leave the phenyl ring unsubstituted. In summary, the instantly claimed compound is an obvious variant over the compound disclosed in the Gordon *et al.* document.

Therefore, applicant's compound would be obvious over the prior art and is rejected.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon *et al.* (WO 97/30053) in further view of Berge *et al.* (Journal of Pharmaceutical Sciences).

Claim 22 is drawn to the hydrochloride salt of the instantly claimed compound in claim 21.

Gordon *et al.* teach what was stated above.

Gordon *et al.* does not teach the hydrochloride salt of said compound.

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Berge *et al.* teaches various pharmaceutical salts. Berge *et al.* mentions that the chemical, biological, and physical properties of medicinal agents can be manipulated by converting them to a salt form (see first paragraph, left column, page 1 of document). Additionally, this document further teaches that commonly FDA Approved commercially marketed salts include hydrochloride salts (see page 2, Table 1, left column).

Therefore, it would have been prima facie obvious to take the compound described in the Gordon *et al.* document, and convert it to its hydrochloride salt to give a compound that would be suitable for medicinal purposes.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon *et al.* (WO 97/30053) in view of Zhu *et al.* (Org. Biomol. Chem.).

Claim 23 is drawn to a preparation of the instantly claimed compound in claim 22.

Gordon *et al.* teach what was stated above.

Gordon *et al.* does not teach the synthesis of said compound using the coupling conditions described in claim 23 (i.e., Boc-L-cystine and a polar aprotic solvent).

Zhu *et al.* describes the coupling of an amine (proline derivative) using Boc-L-cystine in a polar aprotic solvent such as DMF (see page 32, Scheme 1, step (a)). Additionally, the coupling of amines with amino acids is well-documented in



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literature; as well as the conversion of an amine to its hydrochloride salt in a solvent (routine practice in organic chemistry).

Therefore, since the synthetic steps described above are well-known in the literature, the preparation of this compound would have been prima facie obvious.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161